Applicant: Larş Hellman Attorney's Docket No.: 10223-006001

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REMARKS

Claims 25-40 were rejected and remain pending. Claims 25 and 33 have been amended to replace the phrase "consisting essentially of" with the word "comprising" such that the claims are as originally presented. In addition, claims 25 and 33 have been amended to recite that at least one of the non-self IgE domains consists of an IgE sequence present in a non-placental mammal. Finally, claims 27 and 35 have been amended to reflect the "human" version of the immunogenic polypeptide. As amended, claims 27 and 35 recite immunogenic polypeptides having the sequence set forth in SEQ ID NO:8, rather than SEQ ID NO:4. No new matter has been added by these amendments.

In light of these amendments and the following remarks, Applicant respectfully requests reconsideration and allowance of claims 25-40.

<u>Interview summary</u>

Applicant's agents thank Examiner Huynh and Examiner Chan for the courtesy of a telephonic interview on October 27, 2003. The interview included a discussion of the rejections within the outstanding Office Action, as well as a discussion of claim amendments proposed by the Applicant. While no agreement was definitively reached, Applicant thanks Examiner Huynh for agreeing to consider the presented claim amendments and remarks.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 25-40 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner also rejected claims 25-40 under 35 U.S.C. § 112, first paragraph, for lack of written description.

Applicant respectfully disagrees. The specification as originally filed fully enabled and adequately described the previously claimed invention. Claims 25 and 33, however, have been amended to recite that at least one of the non-self IgE domains consists of an IgE sequence present in a non-placental mammal. The specification fully enables and adequately describes the presently amended claims. As explained in the accompanying declaration by Dr. Hellman, a person having ordinary skill in the art would have been able to use common molecular biology techniques to obtain IgE sequences from non-placental mammals. In fact, a graduate student and

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technician in Dr. Hellman's laboratory used a platypus IgE nucleic acid fragment to obtain via standard library screening techniques an IgE sequence from echidna, a non-placental mammal. The obtained echidna IgE sequence was similar to the platypus and opossum IgE sequences provided in the above-referenced patent application. Given this evidence together with the remarks of record, it is clear that Applicant's specification fully enables and adequately describes the presently claimed invention.

In light of the above, Applicant respectfully requests withdrawal of the rejections claims 25-40 under 35 U.S.C. § 112, first paragraph.

The Examiner also rejected claims 25-40 under 35 U.S.C. § 112, first paragraph, for containing new matter. Specifically, the Examiner stated that the phrase "consisting essentially of" in claims 25 and 33 is a departure from the specification and claims as originally filed.

Applicant respectfully disagrees. The specification fully supported the previously claimed invention. To further prosecution, claims 25 and 33 have been amended to replace the phrase "consisting essentially of" with the word "comprising."

In light of these amendments, Applicant respectfully requests withdrawal of the rejection of claims 25-40 under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejected claims 25-26, 28-34, and 36-40 under 35 U.S.C. § 103(a) as being unpatentable over Nissim *et al.* (*EMBO J.* 10:101-107, 1991) in view of United States Patent No. 5,653,980 (the '980 patent), Keegan *et al.* (*Mol. Immunol.* 28:1149-1154, 1991), Presta *et al.* (*J. Biol. Chem.* 269:26368-26373, 1994), Basu *et al.* (*J. Biol. Chem.* 268:13118-13127, 1993), and Hellman *et al.* (in New Horizons in Allergy Immunotherapy, Plenum Press, New York, pp. 337-342, 1996). In the Office Action and during the telephonic interview, the Examiner asserted that the claimed polypeptides are obvious over these references.

Applicant respectfully disagrees and submits that the Examiner has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the art must teach or suggest all limitations of the claim at issue. See, e.g., MPEP § 2143.03. The Nissim *et al.* reference discloses chimeric IgE polypeptides that contain mouse and human IgE sequences.

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Nowhere does the Nissim *et al.* reference, or any of the cited references, teach or suggest a polypeptide containing IgE sequences from a non-placental mammal. In fact, none of the cited references provides an IgE sequence from a non-placental mammal. Thus, the obviousness rejection is improper.

In addition, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify or combine the references. See, e.g., MPEP § 2143.01. The cited references fail to provide any suggestion that would motivate a person having ordinary skill in the art to make or use the presently claimed polypeptides. In fact, at no point does the combination of cited references suggest that a person having ordinary skill in the art should make or use a polypeptide containing an IgE domain from a non-placental mammal. Thus, the presently claimed invention is not obvious.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 25-26, 28-34, and 36-40 under 35 U.S.C. § 103(a).

CONCLUSION

Applicant respectfully requests allowance of claims 25-40. The Examiner is invited to contact the undersigned agent if such would further prosecution. Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: <u>Movember 12, 2003</u>

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